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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,865	09/12/2006	Christoph Karl	27578U	3537

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
12/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,865	KARL ET AL.	
	Examiner	Art Unit	
	Gregg Polansky	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' preliminary amendment, filed 8/018/2006, amending Claims 1-20, is acknowledged.

2. Applicants' Information Disclosure Statement, filed 11/22/2006, is acknowledged and has been reviewed.

3. Claims 1-20 are pending.

4. Claims 1-20 are currently under consideration.

Specification

5. The use of the following trademark has been noted in this application: ROBINUL (see Specification, page 1, 3rd paragraph, last line). It should be written in all capital letters wherever it appears; or alternatively, it should be denoted with the registered trademark symbol, ®, and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 3, and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 2 and 3 contain parenthetical subject matter that renders the claim indefinite because it is unclear whether the subject matter is a claim limitation.

9. Claim 15 recites a "method of treatment of a clinical condition in a mammal, for which a PDE 4 inhibitor and/or an anticholinergic agent is indicated", which renders the claim indefinite. It is unclear what clinical conditions fall within the scope of the instantly claimed subject, making it impossible to ascertain with reasonable precision when the claim is infringed and when it is not.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1 and 15 and dependent Claims 2-14, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for glycopyrronium and roflumilast, and pharmaceutically acceptable salts thereof, does not reasonably provide enablement for solvates and derivatives of those compounds. The Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 1 and 15 and dependent Claims 2-14, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claims recite the compounds, glycopyrronium and roflumilast, and pharmaceutically acceptable salts, solvates and functional derivatives. There is insufficient written basis for solvates and functional derivatives of glycopyrronium and roflumilast in the Specification.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Elli Liily*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66

Fed. Reg. At 1106 (emphasis added)). Moreover, although *Elli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties of solvates of glycopyrronium and roflumilast, aside from a broad recitation that such are contemplated for use in the invention and one example of a functional derivative of roflumilast. As such, it is not apparent that Applicant was actually in possession of, and intended to use within the context of the present invention, any specific functional derivatives (with the exception of the 1-oxide metabolite derivative of roflumilast, disclosed in the Specification on page 4) or solvates of glycopyrronium and roflumilast, at the time the present invention was made.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Maus et al. (U.S. Patent Application Pub. No. 2005/0175547).

Maus et al. teach a combination of an inhaled or oral PDE 4 inhibitor in combination with inhaled muscarinic cholinergic receptor antagonists for the treatment of respiratory diseases, including asthma and chronic obstructive pulmonary disease (COPD). See Abstract. Maus et al. teach the PDE 4 inhibitor, roflumilast, and its physiologically acceptable salts, and the anticholinergic compound, glycopyrronium and its physiologically acceptable salts, including the bromide salt, glycopyrrolate. See Abstract and claims 2 and 4 on page 4). The reference teaches the racemic and R,R-enantiomerically enriched forms of glycopyrrolate. See page 4, claims 2 and 3. Maus et al. teach the two active agents in a fixed or free combination for simultaneous, sequential, or separate administration with pharmaceutically acceptable excipients and additives. See page 4, claim 18. The reference further teaches therapeutically effective dose ranges and schedules for the two agents, including a preferred once or twice daily administration of the agents. See, for example, page 3, paragraphs 26 and 27. The formulation taught by Maus et al. may be administered by inhalation in an aerosol or dry powder form. When used as a powder, an excipient such as lactose monohydrate may be used. See page 3, paragraphs 25 and 26 and claim 12.

All the elements of the instant claims are taught by Maus et al. and are therefore properly rejected under 35 U.S.C. 102(e).

Conclusion

14. Claims 1-20 are rejected.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregg Polansky

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

11/30/07